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Hendriks et al.

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(54) **SYSTEMS AND METHODS FOR CAPTURE AND DISPLAY OF BLOOD PRESSURE AND ULTRASOUND DATA**

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A61B 5/021 (2006.01)
A61B 5/0215 (2006.01)
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(Continued)

(58) **Field of Classification Search**
CPC .. A61B 5/0205; A61B 5/021; A61B 5/0215; A61B 8/08; A61B 8/0883; A61B 8/14; A61B 8/4444; A61B 8/463; A61B 8/486; A61B 8/5284
See application file for complete search history.

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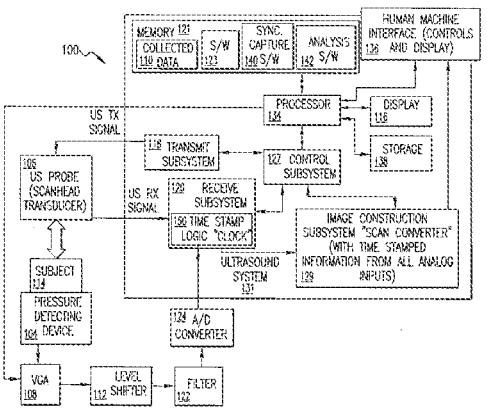
(74) *Attorney, Agent, or Firm* — Perkins Coie LLP

(57) **ABSTRACT**

An ultrasonic imaging system comprises a processing system and an ultrasound imaging probe that is configured to transmit ultrasound energy into a selected portion of a subject and to receive echoes therefrom and to transmit data signals representative thereof to the processing system. The system further comprises a blood pressure sensor that is configured to measure the blood pressure of the subject and to transmit data signals representative thereof to the processing system. The processing system can processes the received ultrasound data signals to generate an ultrasound image and the received blood pressure data signals to generate a blood pressure trace. The processing system can also display the ultrasound image and blood pressure trace in a display image in which portions of the ultrasound image are displayed in temporal synchrony with portions of the blood pressure trace.

13 Claims, 12 Drawing Sheets



(51) **Int. Cl.**

A61B 8/08	(2006.01)
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A61B 8/00	(2006.01)

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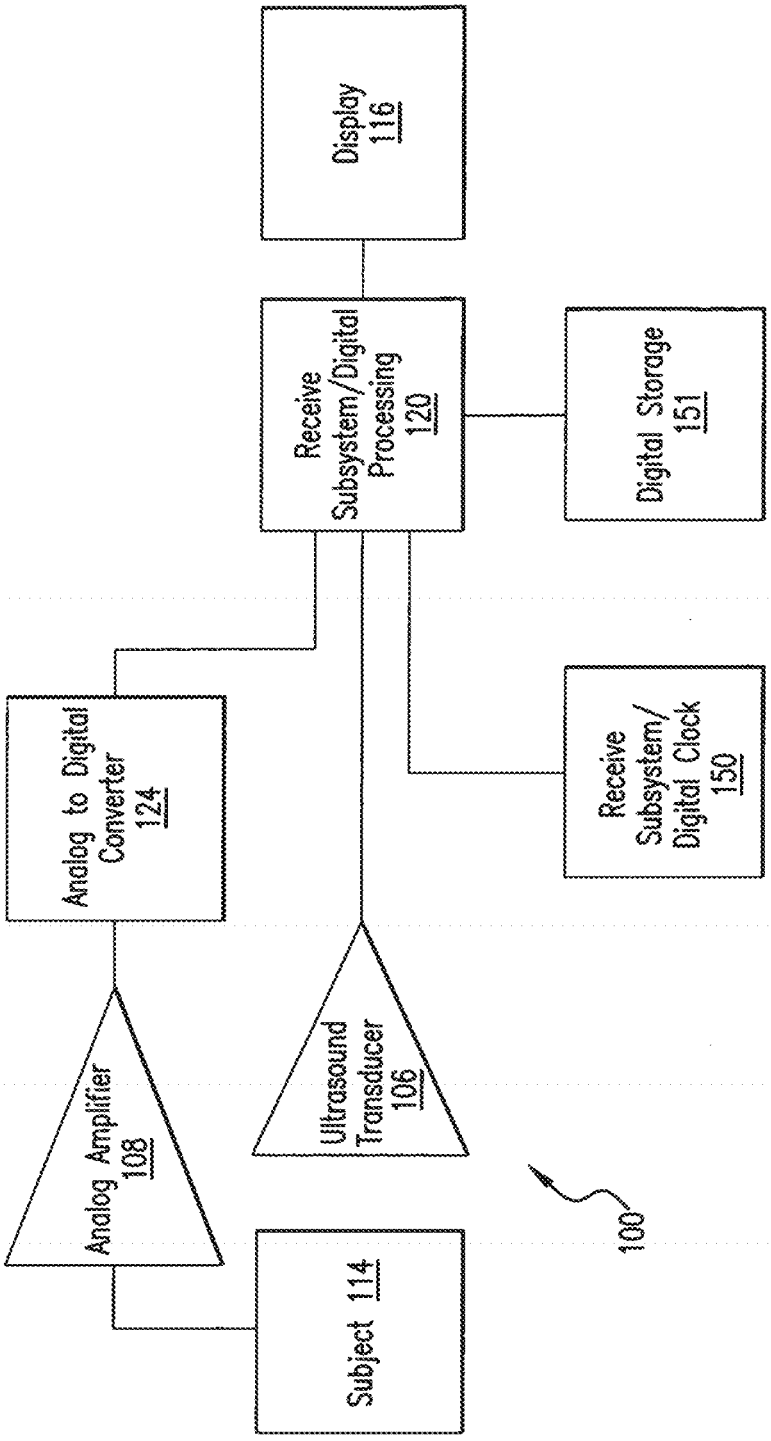
Display
116
Receive
Subsystem/Digital
Processing
120
Digital Storage
151
Analog to Digital
Converter
124
Receive
Subsystem/
Digital Clock
150
Analog Amplifier
108
Ultrasound
Transducer
106
100
Subject 114

FIG. 1

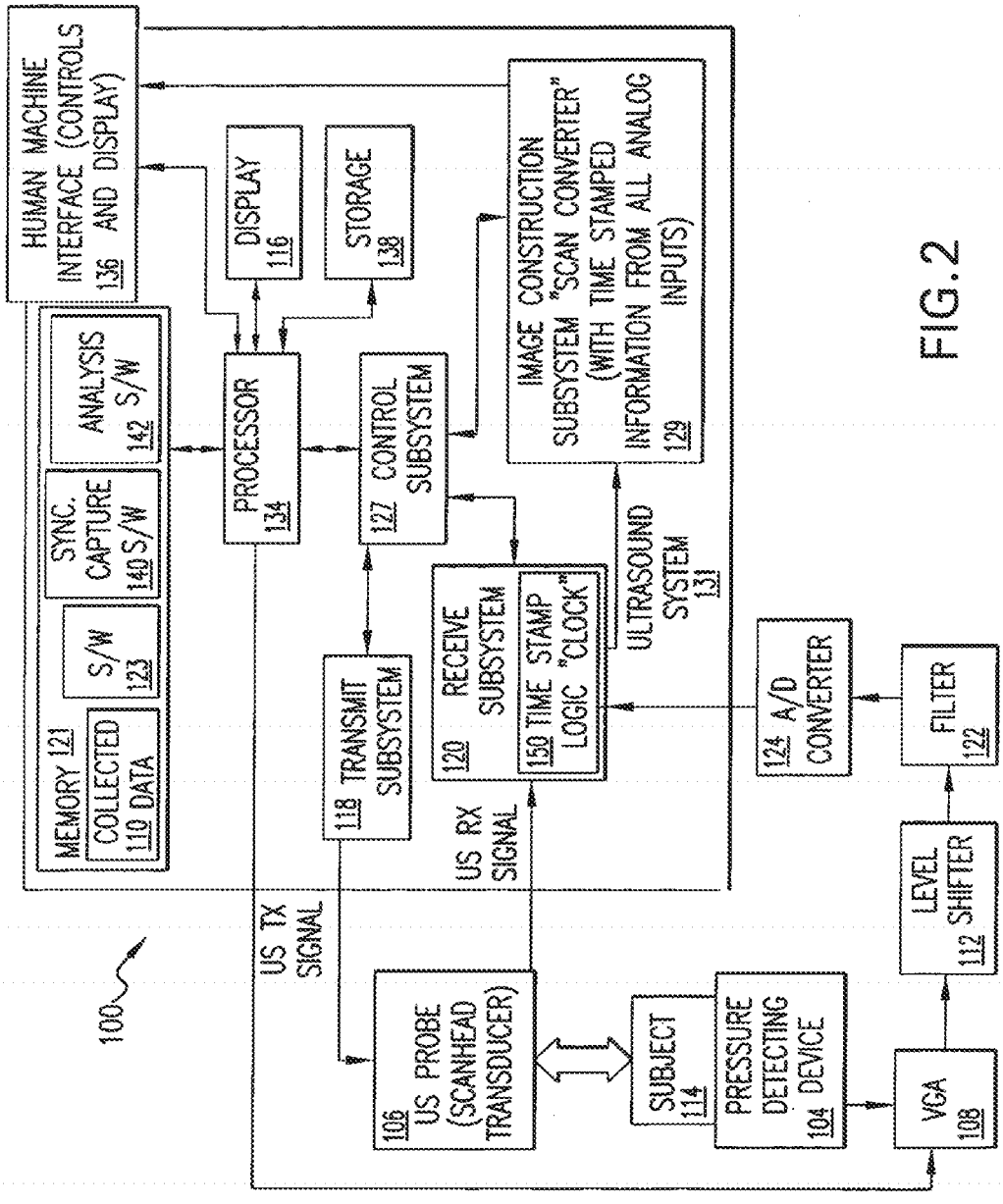
100
HUMAN MACHINE INTERFACE (CONTROLS 136 AND DISPLAY)
DISPLAY 116
STORAGE 138
IMAGE CONSTRUCTION SUBSYSTEM "SCAN CONVERTER" (WITH TIME STAMPED INFORMATION FROM ALL ANALOG INPUTS) 129
MEMORY 121
COLLECTED 110 DATA
S/W 123
SYNC. CAPTURE 140 S/W
ANALYSIS S/W 142
PROCESSOR 134
127 CONTROL SUBSYSTEM
ULTRASOUND SYSTEM 131
120 RECEIVE SUBSYSTEM
150 TIME STAMP LOGIC "CLOCK"
118 TRANSMIT SUBSYSTEM
124 A/D CONVERTER
FILTER 122
LEVEL SHIFTER 112
VGA 108
US TX SIGNAL
US RX SIGNAL
106 US PROBE (SCANHEAD TRANSDUCER)
SUBJECT 114
PRESSURE DETECTING DEVICE 104

FIG. 2

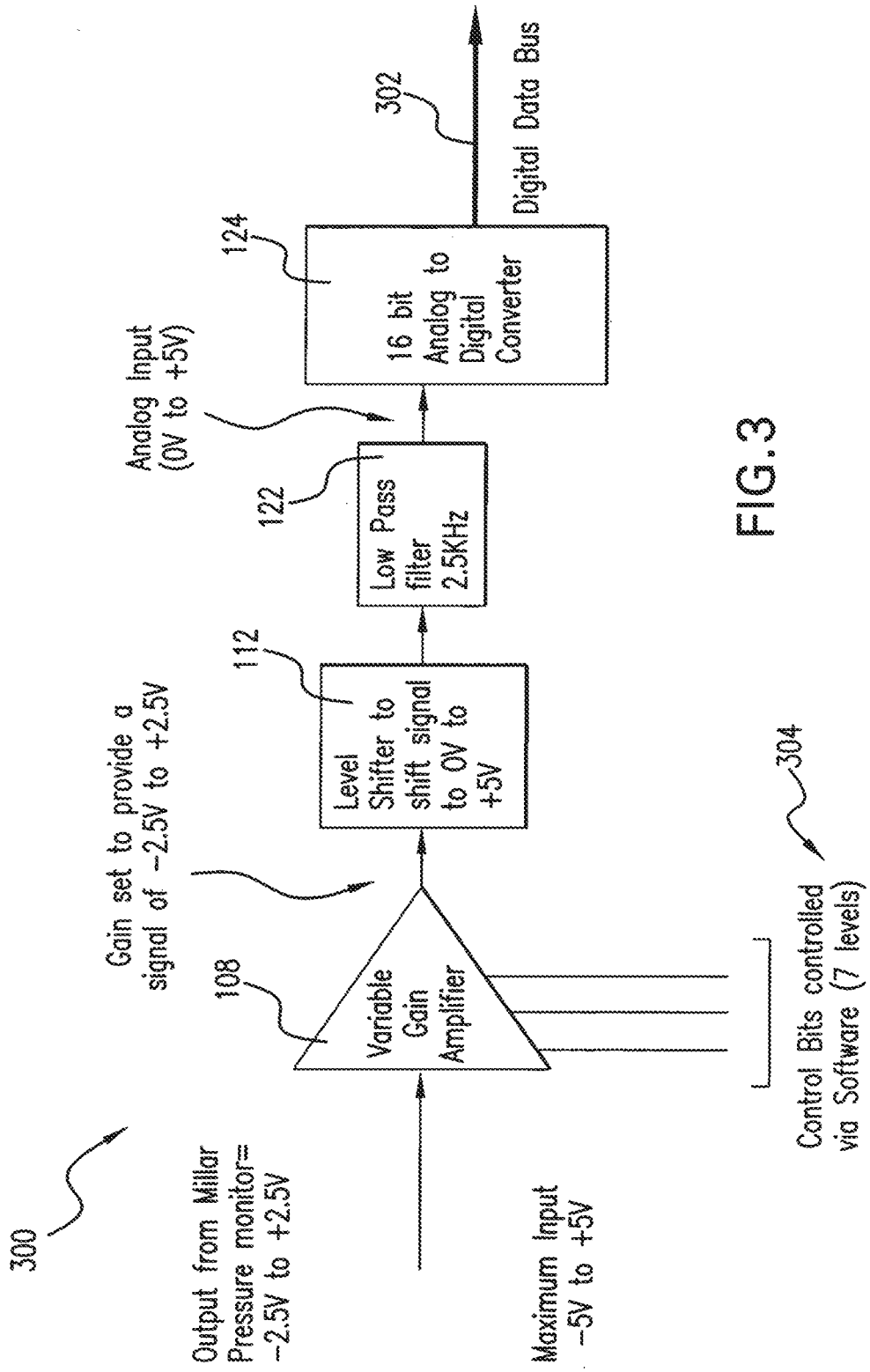
300
Output from Millar Pressure monitor= −2.5V to +2.5V
Maximum Input −5V to +5V
Control Bits controlled via Software (7 levels)
304
108
Variable Gain Amplifier
Gain set to provide a signal of −2.5V to +2.5V
112
Level Shifter to shift signal to 0V to +5V
122
Low Pass filter 2.5KHz
Analog Input (0V to +5V)
124
16 bit Analog to Digital Converter
302
Digital Data Bus

FIG. 3

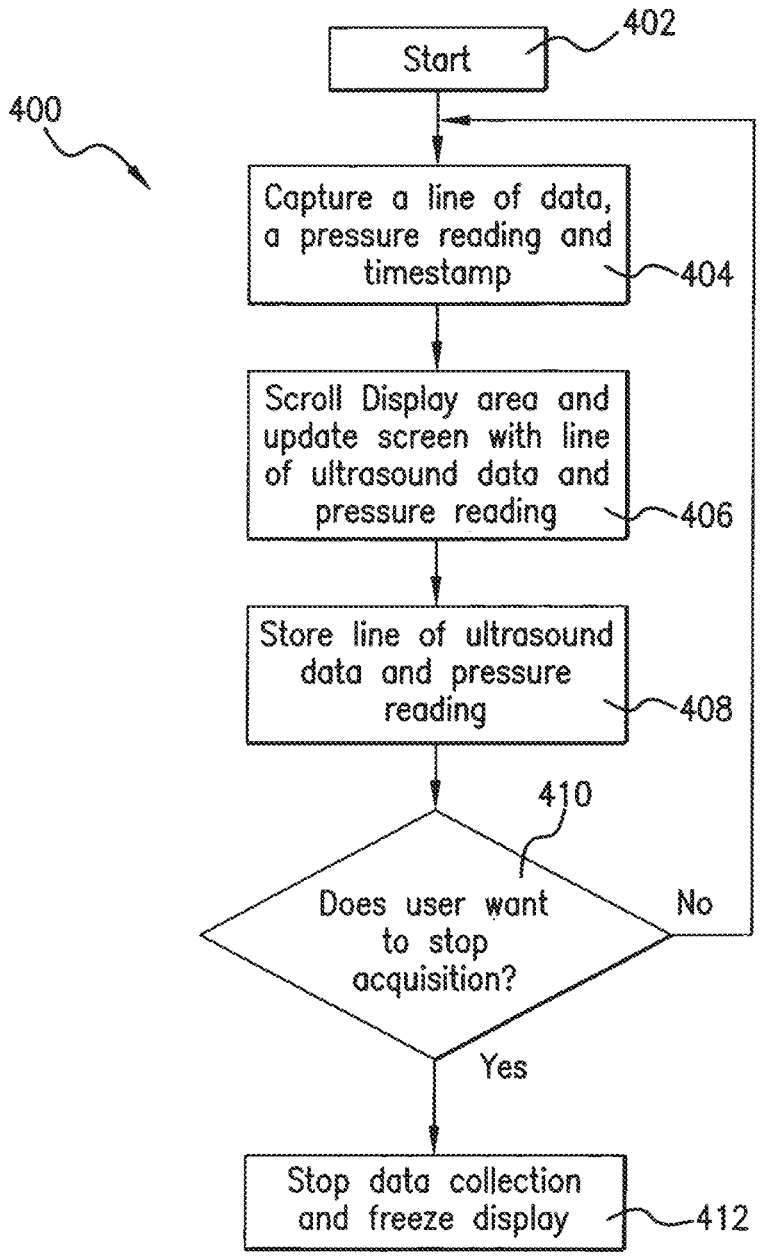
400
Start
402
Capture a line of data, a pressure reading and timestamp
404
Scroll Display area and update screen with line of ultrasound data and pressure reading
406
Store line of ultrasound data and pressure reading
408
410
Does user want to stop acquisition?
No
Yes
Stop data collection and freeze display
412

FIG.4

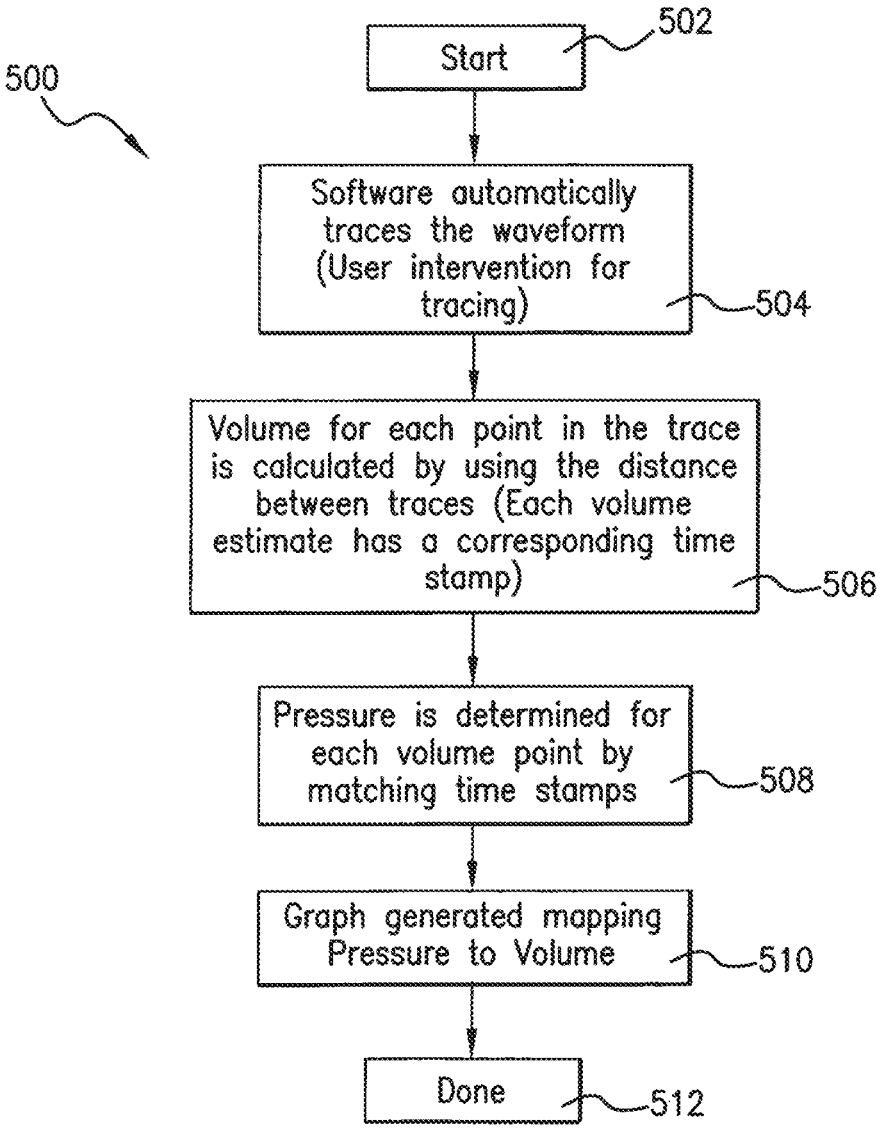
500
Start
502
Software automatically traces the waveform (User intervention for tracing)
504
Volume for each point in the trace is calculated by using the distance between traces (Each volume estimate has a corresponding time stamp)
506
Pressure is determined for each volume point by matching time stamps
508
Graph generated mapping Pressure to Volume
510
Done
512

FIG.5

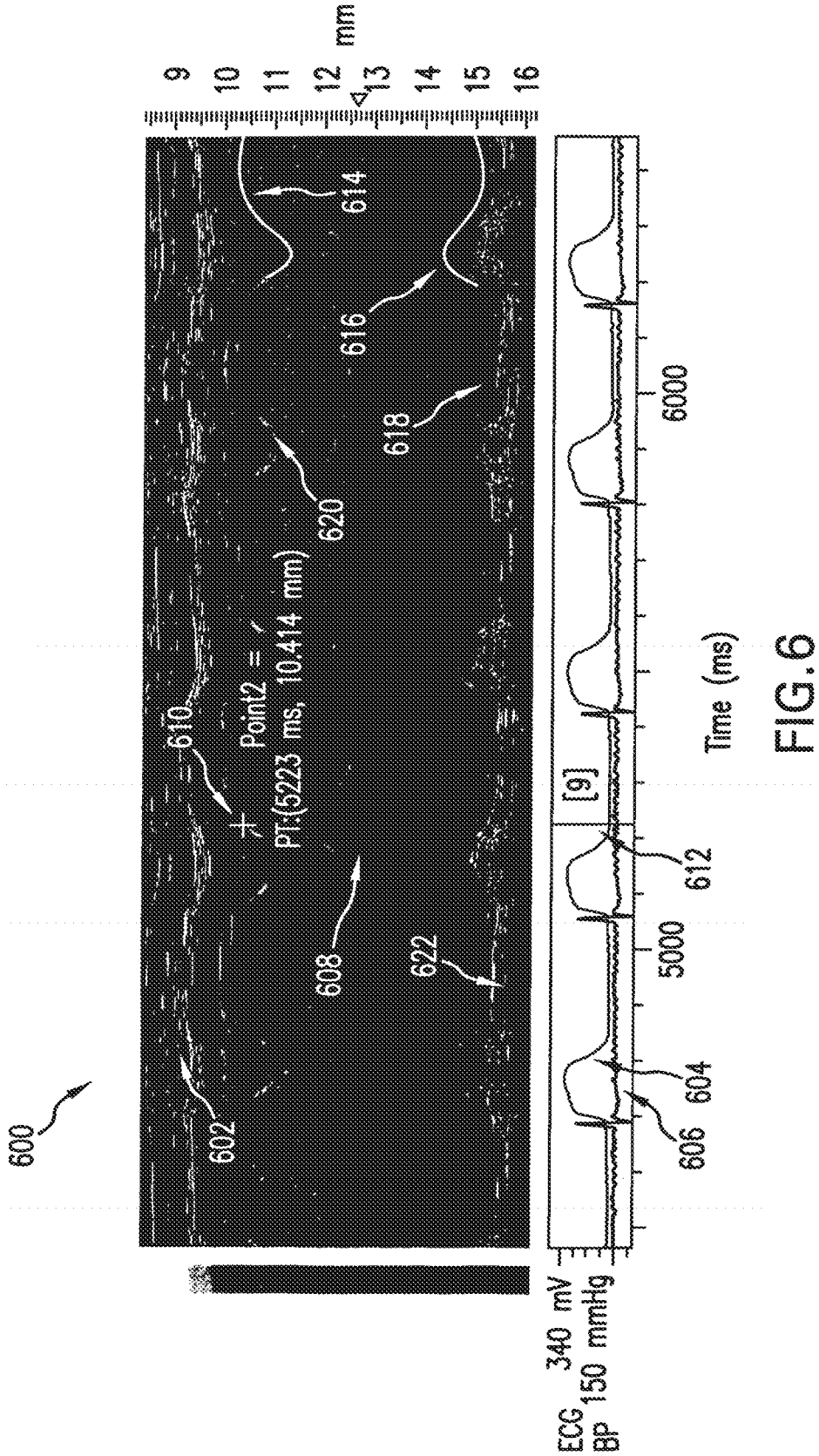
600
602
610
Point2 = (
PT:(5223 ms, 10.414 mm)
608
622
620
618
616
614
9
10
11
12
13
14
15
16
mm
[9]
612
5000
6000
Time (ms)
606
604
ECG 340 mV
BP 150 mmHg

FIG.6

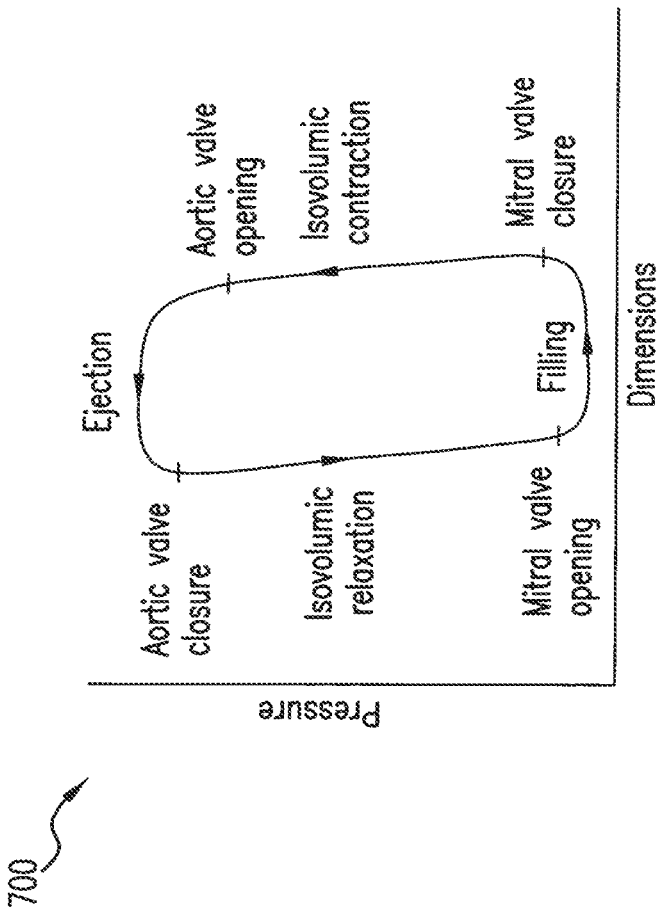
700
Pressure
Dimensions
Aortic valve closure
Isovolumic relaxation
Mitral valve opening
Filling
Ejection
Aortic valve opening
Isovolumic contraction
Mitral valve closure

FIG. 7

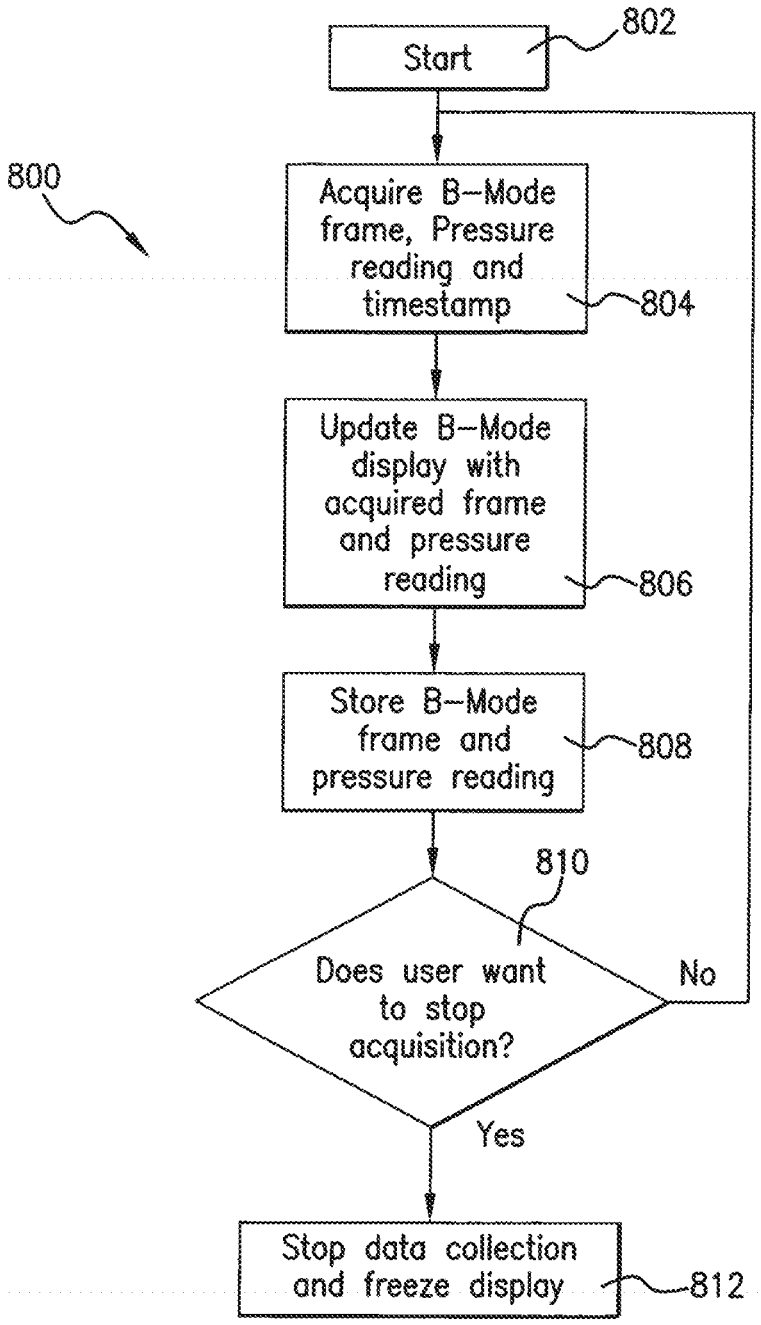
800
Start
802
Acquire B-Mode frame, Pressure reading and timestamp
804
Update B-Mode display with acquired frame and pressure reading
806
Store B-Mode frame and pressure reading
808
810
Does user want to stop acquisition?
No
Yes
Stop data collection and freeze display
812

FIG.8

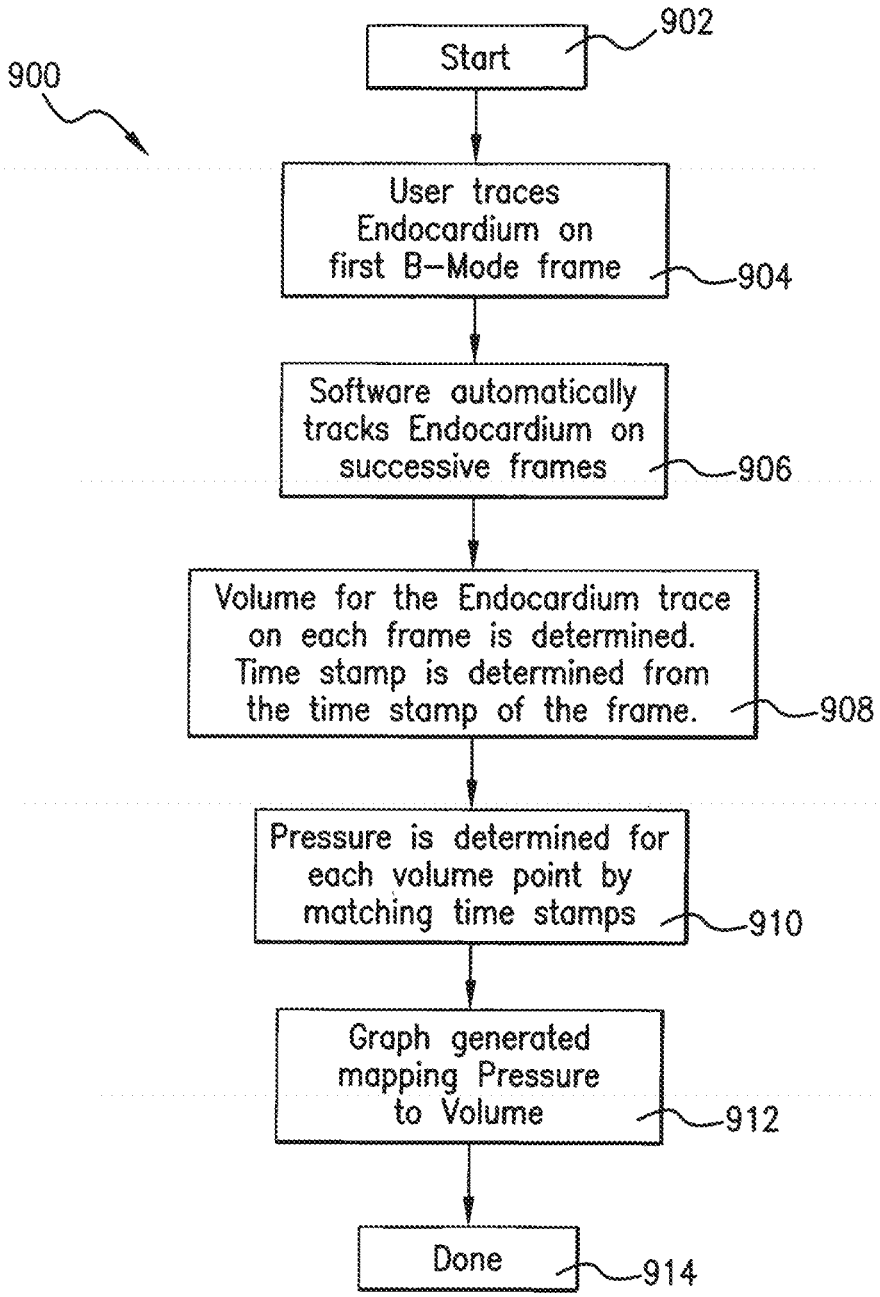
900
Start
902
User traces Endocardium on first B-Mode frame
904
Software automatically tracks Endocardium on successive frames
906
Volume for the Endocardium trace on each frame is determined. Time stamp is determined from the time stamp of the frame.
908
Pressure is determined for each volume point by matching time stamps
910
Graph generated mapping Pressure to Volume
912
Done
914

FIG.9

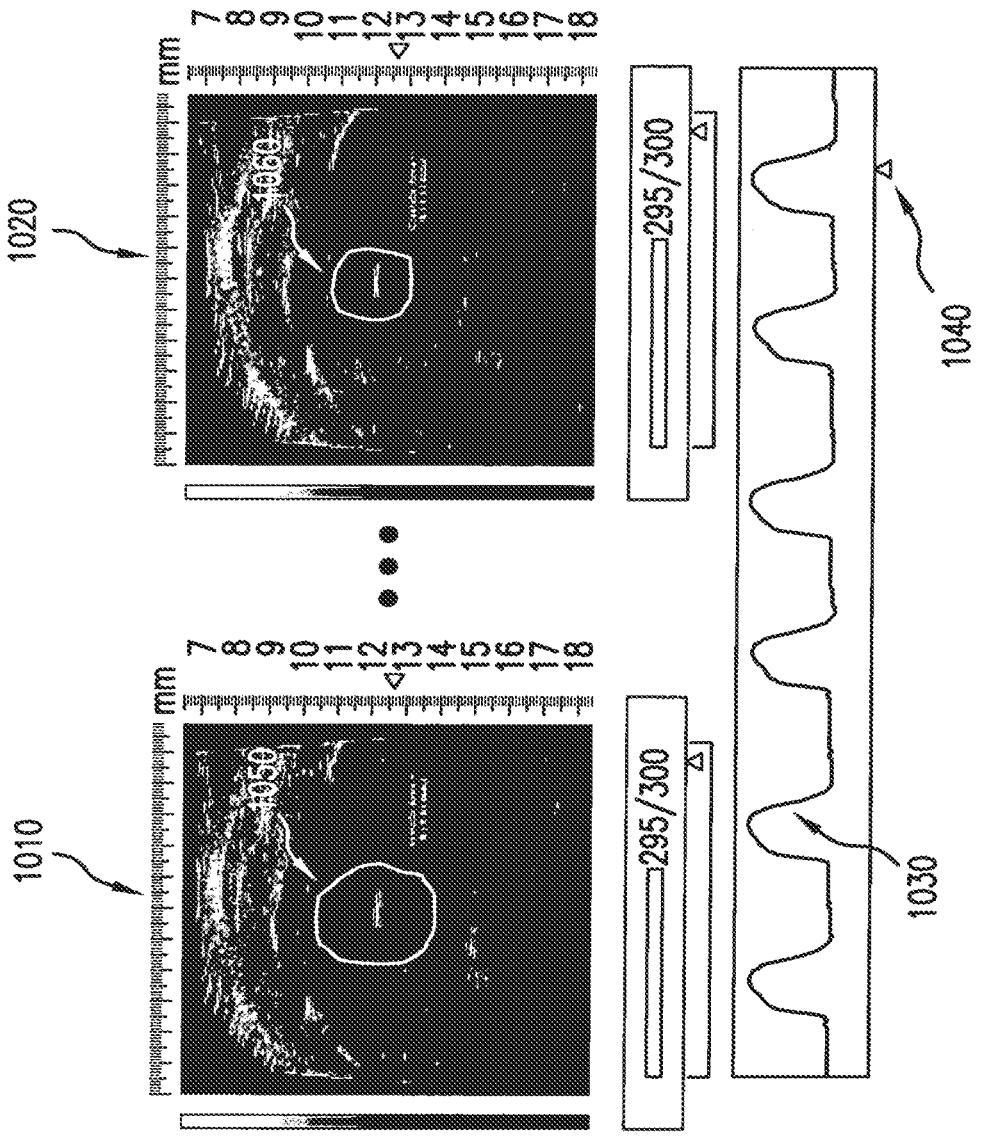
1020
1010
mm
7 8 9 10 11 12 13 14 15 16 17 18
295/300
295/300
1040
1030

FIG.10

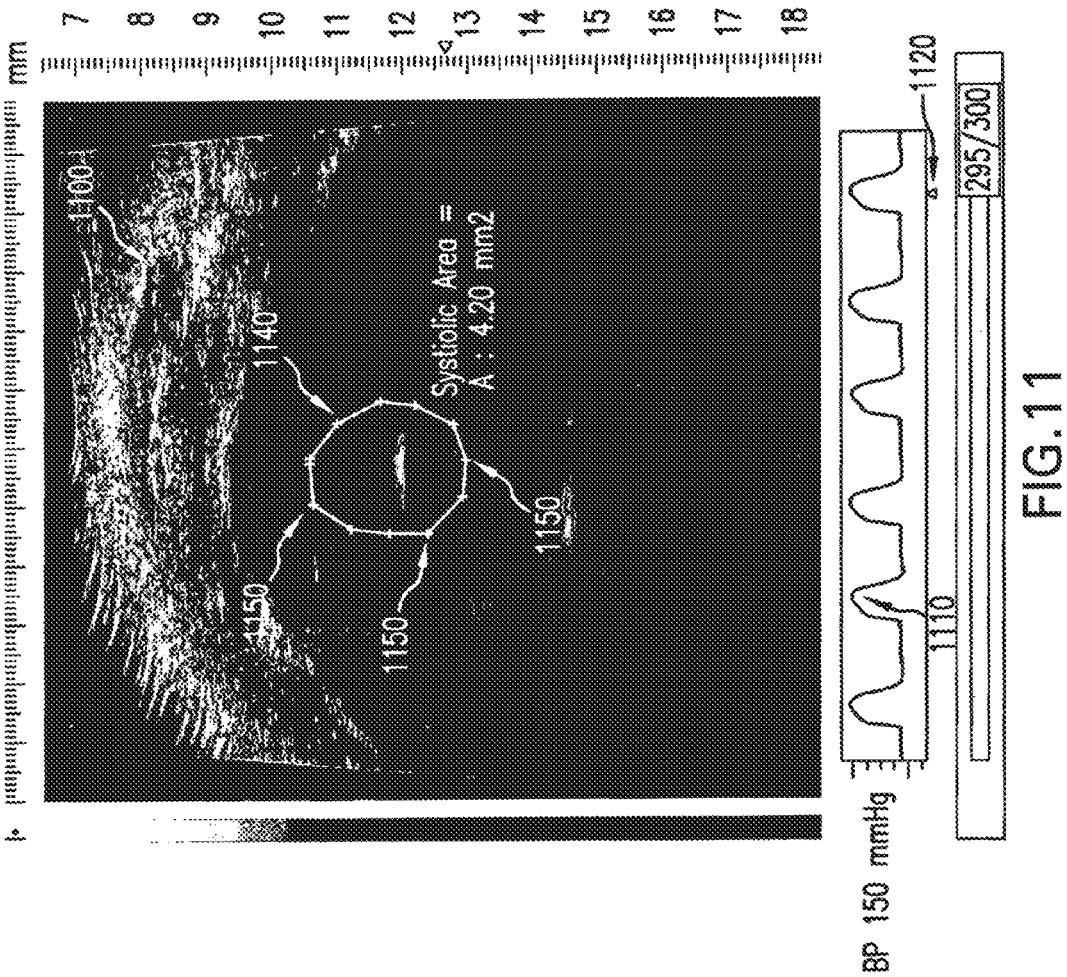
mm
7
8
9
10
11
12
13
14
15
16
17
18
1100
1140
1150
1150
1150
Systolic Area =
A : 4.20 mm2
BP 150 mmHg
1120
1110
295/300

FIG.11

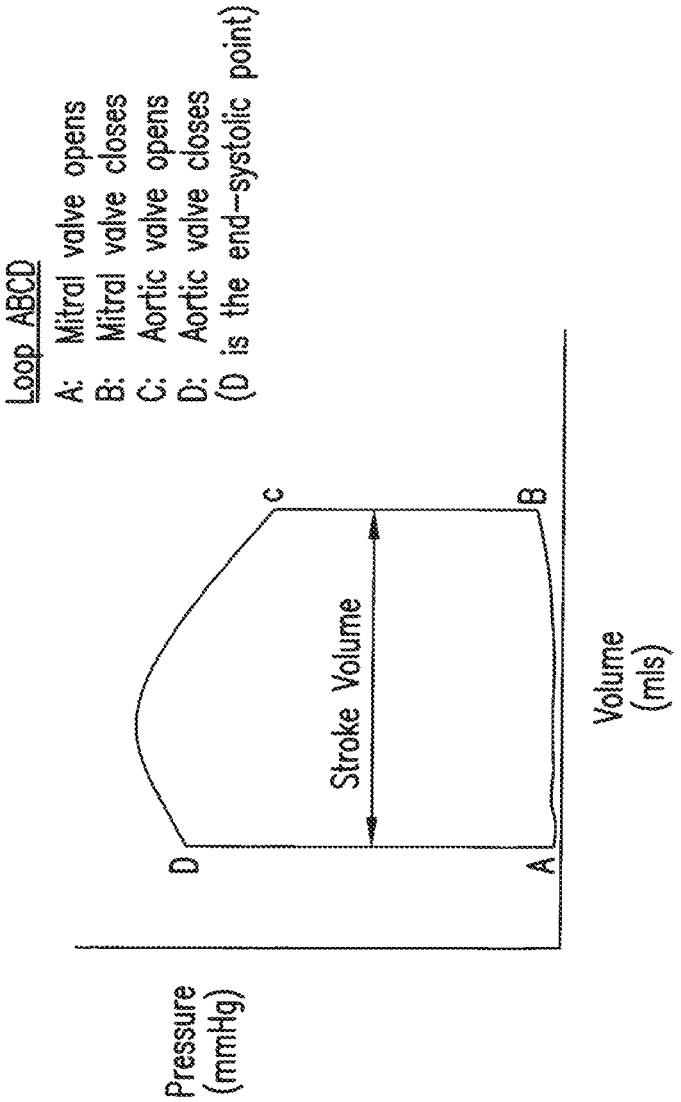
Loop ABCD
A: Mitral valve opens
B: Mitral valve closes
C: Aortic valve opens
D: Aortic valve closes
(D is the end-systolic point)
Pressure (mmHg)
Volume (mls)
Stroke Volume
A
B
C
D

FIG. 12

SYSTEMS AND METHODS FOR CAPTURE AND DISPLAY OF BLOOD PRESSURE AND ULTRASOUND DATA

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a division of U.S. patent application Ser. No. 11/507,068, filed on Aug. 18, 2006, now U.S. Pat. No. 8,317,714, which claims the benefit of U.S. Provisional Application No. 60/709,837, filed on Aug. 19, 2005, which is herein incorporated by reference in its entirety.

BACKGROUND OF THE INVENTION

Assessment of myocardial performance, function and contractility is critically important for the evaluation of many patients with known or suspected heart disease. There has been vowing interest in the dynamic assessment of cardiac contraction relying on the instantaneous relationships between pressure and dimensions in both the left and right ventricles.

Pressure-volume or pressure-dimension loops provide visual and parametric information regarding the performance of the right and left ventricle as a pump and help identify the pathophysiology of cardiac dysfunction and the extent of cardiac impairment. Moreover, these loops allow for determination and quantification of the success of many therapeutic interventions. Thus, accurate and efficient analysis of pressure and dimension relationships in the heart of patients and in clinical research using small animal subjects is critically important for assessing disease, response to therapeutics, and for developing new therapeutics and strategies for treating human and animal patients.

Current methods in the art for assessing pressure-volume or pressure-dimension relationships, including traditional echocardiography and conductance methods, can be overly complicated, time consuming and unreliable. Needed in the art are systems and methods for capture and display of blood pressure and ultrasound data.

SUMMARY OF THE INVENTION

A method for the capture and display of ultrasound data and blood pressure data from a subject comprises capturing ultrasound data and blood pressure data from the subject. The captured ultrasound and blood pressure data can be time-stamped. The time-stamped ultrasound data and the time-stamped blood pressure data can be processed for display on a display device and the processed data can be displayed synchronously on the display device.

A system for the capture and display of ultrasound data and blood pressure data from a subject can comprise an ultrasonic transducer capable of transmitting ultrasound into the subject and of receiving echo data from the subject. The system can further comprise a blood pressure receiving mechanism capable of collecting blood pressure data from the subject and a processing system for receiving the echo data and the collected blood pressure data. The processing system can be further used to identify the received data with a time-stamp, and to display synchronously the time-stamped ultrasound and blood pressure data on a display device.

Other systems, methods, and aspects and advantages of the invention will be discussed with reference to the Figures and to the detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be described by way of example, in the detailed description, with particular reference to the accompanying Figures in which:

FIG. **1** is a block diagram illustrating an exemplary imaging system.

FIG. **2** is a block diagram further illustrating the exemplary imaging system of FIG. **1**.

FIG. **3** is a schematic diagram illustrating portions of the exemplary imaging system of FIG. **1** and FIG. **2**.

FIG. **4** is a block diagram illustrating an exemplary method for the capture and display of M-mode ultrasound data and blood pressure data using the exemplary system of FIG. **1** and FIG. **2**.

FIG. **5** is a block diagram illustrating an exemplary method of processing an M-mode ultrasound image and blood pressure data using the exemplary system of FIG. **1** and FIG. **2**.

FIG. **6** is an image of an exemplary display of M-mode ultrasound data, blood pressure data, and ECG data produced using the exemplary system of FIG. **1** and FIG. **2**.

FIG. **7** is a schematic showing a pressure dimension loop graph and associated events in a typical cardiac cycle.

FIG. **8** is a block diagram illustrating an exemplary method for the capture and display of a B-mode frame or B-mode frames and blood pressure data using the exemplary system of FIG. **1** and FIG. **2**.

FIG. **9** is a block diagram illustrating an exemplary method of processing a B-mode frame or B-mode frames and blood pressure data using the exemplary system of FIG. **1** and FIG. **2**.

FIG. **10** is a schematic diagram illustrating two exemplary B-mode frames and an exemplary blood pressure waveform.

FIG. **11** is an image of an exemplary display comprising a B-mode frame and blood pressure data produced using the exemplary system of FIG. **1** and FIG. **2**.

FIG. **12** is a schematic showing a pressure volume loop graph and associated events in a typical cardiac cycle.

DETAILED DESCRIPTION OF THE INVENTION

Provided herein are systems and methods for capture and synchronous display of blood pressure and ultrasound data. These methods and systems allow for accurate determination of pressure-volume or pressure-dimension relationships in the cardiovascular system of human patients and small animal subjects.

As used throughout, the singular forms "a," "an" and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a processor" can include two or more such processors unless the context indicates otherwise.

By a "subject" is meant an individual. The term subject includes small or laboratory animals as well as primates, including humans. A laboratory animal includes, but is not limited to, a rodent such as a mouse or a rat. The term laboratory animal is also used interchangeably with animal, small animal, small laboratory animal, or subject, which includes mice, rats, cats, dogs, fish, rabbits, guinea pigs, rodents, etc. The term laboratory animal does not denote a particular age or sex. Thus, adult and newborn animals, as well as fetuses (including embryos), whether male or female, are included.

"Blood pressure" or "pressure" are used interchangeably herein and refer to the detectable pressure exerted by the circulating blood of a subject on the walls of the vessels or of the heart of the subject.

Provided herein is a method for the capture and display of ultrasound data and blood pressure data from a subject comprising capturing ultrasound data and blood pressure data from the subject. Optionally, the blood pressure and ultrasound data can be captured simultaneously from the subject. The captured ultrasound and blood pressure data can be time-stamped, and the time-stamped data can be processed for display on a display device. Optionally, the time-stamped ultrasound data and the time-stamped blood pressure data are displayed synchronously on the display device.

"Synchronous display" or "displayed synchronously" means blood pressure and ultrasound data can be displayed simultaneously on a display device. The ultrasound data can also be displayed synchronously such that a time stamped B-mode frame or line of M-mode data can be displayed with a corresponding time stamped blood pressure data point. Such data can be considered to he in temporal synchrony. In one aspect, a processing system processes received ultrasound data signals to generate an ultrasound image and received blood pressure data signals to generate a blood pressure trace. The processing system can display the ultrasound image and blood pressure trace in a display image in which portions of the ultrasound image are displayed in temporal synchrony with portions of the blood pressure trace. For example, the processing system can be used to display an ultrasound image and a blood pressure trace in a display image in which portions of the ultrasound image having a given temporal identity are displayed with portions of the blood pressure trace having the same temporal identity.

Thus, portions of the ultrasound image can be displayed in temporal synchrony with portions of the blood pressure trace. A portion of the ultrasound image having a given temporal identity can be at least one line of ultrasound data signals. The at least one line can comprise an M-Mode ultrasound image. A portion of the ultrasound image having a given temporal identity can also be at least one frame of ultrasound data signals. For example, a frame of ultrasound data can comprise a B-Mode ultrasound image.

An ultrasound image or a portion thereof having a given temporal identity can be correlated with a blood pressure trace or a portion thereof having the same temporal identity. A plurality of ultrasound data signals and a plurality of blood pressure data signals can be correlated, each respective signal having a given temporal identity, by identifying respective data signals and pressure signals having the same temporal identities.

Capturing of echo signals or ultrasound data can comprise generating ultrasound, transmitting ultrasound into the subject, and receiving echos reflected by the subject. Received echoes can be used to produce an ultrasound image or portions thereof. A wide range of frequencies of ultrasound can be used to capture ultrasound data. For example, clinical frequency ultrasound (less than 20 MHz) or high frequency ultrasound (equal to or greater than 20 MHz) can be used. One of skill in the art can readily determine what frequency to use based on factors such as, for example, but not limited to, depth of imaging, or desired resolution.

High frequency ultrasound may be desired when high resolution imaging is desired and the structures to be imaged within the subject are not at too great a depth. Thus, capturing ultrasound data can comprise transmitting ultrasound having a frequency of at least 20 MHz into the subject and receiving a portion of the transmitted ultrasound that is reflected by the subject. For example, a transducer having a center frequency of about 20 MHz, 30 MHz, 40 MHz or higher can be used.

High frequency ultrasound transmission is often desirable for the imaging of small animals, where a high resolution may be achieved with an acceptable depth of penetration. The methods can therefore be used at clinical or high frequency on a small animal subject. Optionally, the small animal is selected from the group consisting of a mouse, rat, and rabbit.

Moreover, the methods and systems are not limited to any particular type of transducer. Any transducer capable of transmitting ultrasound at clinical or high frequency can be used. Many such transducers are known to those skilled in the art. For example, for high frequency transmission, transducers such as those used with the VisualSonics Inc. (Toronto, Calif.), Vevo®660 or Vevo®770 high frequency ultrasound systems can be used. High frequency and clinical frequency arrayed transducers and systems can also be used.

The ultrasound data can be captured as a line of ultrasound data or as a frame of ultrasound data. For example, a line of ultrasound can be captured in M-mode or a frame of ultrasound can be captured in B-mode. The captured ultrasound and blood pressure data can be time-stamped by using a digital clock. Optionally, the same digital clock can be used to time-stamp the captured ultrasound data and the blood pressure data. The ultrasound data can be displayed as an M-mode image or a B-mode frame or image and the pressure data can be displayed as a pressure waveform. Both the ultrasound data and the blood pressure data can be displayed on a display device.

The methods and systems can be used to image an organ located within a subject, or a portion thereof. Moreover, the organ, or portion thereof, can be imaged over time. For example, an M-mode image may comprise a two dimensional representation (depth and time) of an organ located within the subject, or a portion thereof, which can be produced from collected ultrasound data. M-mode imaging is a well known method to those of skill in the art. The image can also comprise a B-mode frame. One or more B-mode frames can be viewed in series to produce a loop of B-mode frames. B-mode imaging and the production of loops from B-mode frames are techniques known to those skilled in the art.

Many different organs of interest can be imaged including dynamic organs having a lumen. For example, a heart, or a portion thereof, can be imaged using the methods and systems described herein. The methods and systems are not limited to imaging the heart, however, and other organs, including other portions of the cardiovascular system can be imaged. Thus, for example, portions of the aorta can be imaged and analyzed.

Provided herein are methods that further comprise determining a dimension of an organ, or a portion thereof, at a point in time. The dimension can be determined by determining the distance between a first trace made on an M-mode image and a second trace made on the M-mode image, wherein the traces made correspond to at least one point in time.

A dimension of an organ or portion thereof at a point in time can be measured by measuring the distance between a first selected portion of an M-mode image having a temporal identity; and a second selected portion of the M-mode image having the same temporal identity, wherein the measured distance provides the dimension of the organ or portion

thereof. The determined dimension at the point in time can be compared with a pressure reading taken at the same point in time to determine a pressure dimension relationship for that point in time. In one aspect, a further dimension of an organ or portion thereof at least at one subsequent point in time can be calculated from the distance between a first trace made on the M-mode image and a second trace made on the M-mode image, wherein the traces correspond to the at least one subsequent point in time.

Thus, a user can trace a structure located on an M-mode image using automated or semi-automated software. The user can also trace a second structure that is spaced some distance from the first tracing as viewed on the M-mode image display. The first and second trace are therefore separated by a distance (d). This distance may span a lumen, if an organ comprising a lumen is imaged. For example, if a portion of the heart is imaged, as is typical in M-mode echocardiography, a luminal wall of the heart is distinguishable from the lumen and from a corresponding luminal wall. Thus, a chamber of the heart, such as a ventricle can be imaged by M-mode ultrasound, which provides a cross sectional image wherein structures reflecting the transmitted ultrasound are displayed based on their distance from the transducer.

As show in FIG. **6**, an M-mode display shows a wall **602** of a heart chamber having a surface **620** overlying a lumen **608**, and the lumen overlies a wall **622** of the heart having a second surface **618**. As the M-mode image scrolls, one imaged portion of the heart is imaged dynamically over time and the contraction and relaxation of the heart walls can be visualized and/or the narrowing and expansion of the lumen can be visualized in real time at that anatomic cross section of the heart.

The disclosed methods can further comprise comparing the determined dimension of the organ, or portion thereof, at the point in time with a pressure reading taken at the, same point in time to determine a pressure dimension relationship for that point in time. A dimension of the organ or portion thereof can be determined at least at one subsequent point in time by calculating the distance between a first trace made on the M-mode image and a second trace made on the M-mode image, wherein the traces correspond to the at least one subsequent point in time. The determined dimension at the at least one subsequent point in time can be compared with a pressure reading taken at the same point in time to determine a pressure dimension relationship for that point in time. Optionally, the pressure dimension relationship is a pressure to diameter relationship. Optionally, the pressure to diameter relationships are determined at a plurality of time points and are expressed as a pressure to dimension loop. Moreover, a volume of an imaged object can be determined from the M-mode image and a pressure to volume relationship can be determined. For example, in M-Mode the volume of an object or portion thereof, for example, a ventricle, can he estimated using the Teicholz formula:

$$v = \frac{7.0}{2.4 + d} \times d^3$$

Where:

v is the estimated volume in micro liters

d is the dimension in millimeters of the ventricle measured on the M-Mode image.

The methods described herein can also comprise determining an area or volume of an organ, or a portion thereof, at a point in time using one or more B-mode frames. The area and/or volume can be determined using a B-mode frame comprising an image of an organ or a portion thereof. For example, the imaged organ can comprise a lumen wherein the displayed B-mode frame or image is a cross sectional representation of the organ. Optionally, the organ is a heart. Exemplary B-mode frames comprising an image of a heart chamber are shown in FIG. **10** and FIG. **11**.

A portion of the B-mode frame oh the display device can be traced. The tracing can substantially follow a portion of the B-mode frame representing a luminal surface of the imaged organ to define an area. For example, the cross sectional shape of a chamber of a heart can be traced. Exemplary B-mode frames comprising an image of a heart chamber with a tracing substantially following the endocardium are shown in FIG. **10** and FIG. **11**. Based on the traced area of the B-mode frame, the size of the area defined by the trace can also be determined. A volume corresponding to the area can be determined.

For example, in B-Mode the volume can be estimated using the Simpson's method. In this method, a long axis view of the ventricle is mathematically sliced as shown in the following diagram. The volume of each slice can be computed and then summed to produce the final volume. For example, the following equation can be used:

$$Vol = \sum_{i=1}^{n} \pi \times \left(\frac{d_i}{2}\right) \times h$$

Where;

v is the estimated volume in micro liters

d is the diameter in millimeters of each slice of the ventricle.

n is the number of slices

h is the spacing between the slices.

The determined volume can be compared with a blood pressure reading having the same time-stamp as the B-mode frame from which the volume was determined to determine a pressure volume relationship. Moreover, a volume can be determined from at least one subsequently displayed time-stamped B-mode frame and the volume determined from the subsequent frame can be compared with a pressure reading having the same time-stamp as the subsequent frame to determine a corresponding pressure volume relationship. The pressure volume relationship from a plurality of time points can be displayed as a pressure to volume loop.

A system for the capture and display of ultrasound data and blood pressure data from a subject comprises an ultrasonic transducer capable of transmitting ultrasound into the subject and of receiving reflected echo data or signals from the subject. The system can further comprise a blood pressure receiving mechanism or sensor capable of collecting blood pressure data from the subject and a processing system for receiving the reflected ultrasound data or echoes and the collected blood pressure data and for generating an image. The ultrasound data and the blood pressure data can he displayed synchronously on a display device. The transducer can be an array, a single element or another type of transducer. An array or non-array transducer can transmit clinical and/or high frequency ultrasound. Thus, the center frequency of the transducer may be at 20 MHz or higher or may be less than 20 MHz. The transducer can be a broadband transducer.

The processing system can be used or programmed for determining a pressure dimension relationship from the

synchronously displayed ultrasound and blood pressure data. The processing system can comprise one or more processors. As one of skill in the art would recognize, where a single processor or processing system is described for performing multiple functions, multiple processors could be used for performing the same functions separately, and a combination of multi-functional and single function processors could also be used.

The processing system can be use or programmed for determining a dimension of the organ or portion thereof at a point in time by calculating the distance between a first trace made on an M-mode image and a second trace made on the M-mode image, wherein the traces comprise representative data from received echo data at one or more point in time. Moreover, the processing system can be used or programmed for comparing the determined dimension at the point in time with a pressure reading taken at the same point in time to determine a pressure dimension relationship for that point in time. The processing system can also be used or programmed for determining a dimension of the organ or portion thereof at least at one subsequent point in time by calculating the distance between a first trace made on an M-mode image and a second trace made on the M-mode image, wherein the traces comprise data representative of echo data corresponding to at least one subsequent point in time. The processing system can be used or programmed for comparing the determined dimension at the at least one subsequent point in time with a pressure reading taken at the same point in time to determine a pressure dimension relationship for that point in time. Optionally, the pressure dimension relationship is a pressure to diameter relationship. Optionally, the pressure to diameter relationships are determined at a plurality of time points and are expressed as a pressure to dimension loop.

The processing system can also be used or programmed for tracing a portion of a B-mode frame of an organ or portion thereof on a display device. If the organ comprises a lumen, for example a heart chamber, the tracing can substantially follow a portion of the frame representing a luminal surface of the imaged organ to define an area as shown in FIGS. **10** and **11**. The processing system can be further used or programmed for determining the size of the defined area and for determining a volume corresponding to the defined area. The processing system can be further used or programmed for comparing the determined volume with a pressure reading having the same time-stamp as the B-mode frame from which the volume was determined to determine a pressure volume relationship. The processing system can he further used or programmed for determining a volume from at least one subsequently displayed time-stamped B-mode frame and comparing the volume determined from the subsequent frame with a pressure reading having the same time-stamp as the subsequent frame to determine a subsequent pressure volume relationship. The processing system can be used or programmed for expressing the pressure volume relationship from a plurality of time points as a pressure to volume loop.

Further provided herein is a system for the capture of ultrasound echo data and blood pressure data from a subject, comprising an ultrasonic transducer capable of transmitting ultrasound into the subject and of receiving reflected echo data from the subject. The system can further comprise a processing system for receiving the reflected echo data and for receiving blood pressure data collected from the subject.

Also provided herein is a system for the capture of echo data and blood pressure data from a subject, comprising a processor programmed for receiving echo data and for receiving blood pressure data collected from the subject.

FIG. **1** shows an exemplary ultrasound system **100** for the capture and display of blood pressure data with ultrasound image data. The ultrasound system **100** operates on a subject **114**. The subject **114** can be a small animal, such as mouse, rabbit or rat, or the subject **114** can be a primate, such as a human.

A blood pressure signal can be obtained from the subject **114** using a blood pressure monitoring or detecting device. Such devices and methods are known in the art. For example, a Millar® catheter (Millar Instruments, Inc. Houston, Tex.), which converts blood pressure to an electric signal, can be used by inserting or positioning a catheter into the subject to acquire blood pressure data. The blood pressure data or signal from the subject can be converted into an analog waveform by the pressure detecting device.

Another example of pressure detecting device is a tail cuff If the subject **114** is a small animal having a tail, a tail cuff may he placed around the tail and pressure data may be obtained using methods known to those skilled in the art. Furthermore, an implant may be used with an RF link that transmits blood pressure data from any point in the body. Thus, known methods and apparatuses for collecting blood pressure signals and for converting blood pressure signals into analog waveforms can be used in the ultrasound system **100**. It is contemplated that any conventional device or method to collect a blood pressure signal from a subject and to convert it into an analog waveform can be used with the ultrasound system **100**.

The analog waveform representing blood pressure data collected from the subject can be delivered into an analog amplifier **108**. An exemplary analog amplifier is described in greater detail below. Analog pressure data can be processed and converted to digital data by an analog to digital converter **124** for provision to the ultrasound system **131**, as shown in FIG. **2**. The ultrasound system **131** is one example of a processing system that can be used. Digital data converted from analog data by the analog to digital converter **124** can be delivered to the receive subsystem **120** where digital processing occurs. Digital processing includes time-stamp logic or a time-stamp clock, which can be viewed as subcomponent **150** of the receive subsystem **120**. Thus, the data from the analog to digital converter **124** can delivered to digital processing (see subsystem **150**) and can be given a time stamp indicating a temporal characteristic of the data, i.e., the point of time at which that particular data was received by the receive subsystem of the ultrasound system.

In addition to the receipt of blood pressure data, the imaging system **100** collects ultrasound image data received by the ultrasound transducer **106**, which can transmit and receive ultrasound of clinical or high frequency. Received echoes reflected from the subject or portions thereof can be converted into an ultrasound receive signal that can be delivered to the receive subsystem **120**. At block **120**, the received ultrasound signal can be converted to digital data and can be time-stamped using the same time stamp logic **150** (FIG. **2**) or clock that stamps the digital blood pressure data. Thus, at block **120**, both blood pressure and ultrasound digital data are identified with a time stamp. Time-stamped data from the receive subsystem **120** can be stored in digital storage **151** which may include temporary storage in the random access memory **121** (FIG. **2**) or on the hard drive **138** (FIG. **2**) of the computer.

Image and blood pressure data can he displayed on a display **116**. For example, image data can be displayed as an

M-mode image as shown in FIG. **6** or as a B-mode frame as shown in FIG. **10** and FIG. **11**. Pressure data can be matched and displayed synchronously with the M-mode image or B-mode frame. Thus, a synchronous display of an ultrasound image and a blood pressure waveform can be represented on the display.

Other sources of data can also he received from the subject **114**, including ECG, respiration, and temperature data. These additional sources of data can be collected as analog data from the subject and converted to digital data by the analog to digital converter **124** for provision to the ultrasound system **131**. This additional data can also be time-stamped at the receive subsystem **120** and can he displayed synchronously with a pressure waveform and M-mode or B-mode ultrasound image.

The synchronous display of the blood pressure data with the M-mode or B-mode ultrasound image allows for accurate pressure/dimension or pressure/volume measurements and/or estimations to be made. Moreover, the synchronous display with other received data from the subject, such as ECG data, allows concurrent analysis of pressure/dimension/volume with heart electrical activity or with the respiration cycle.

The blood pressure data can be matched and synchronously displayed with a corresponding vertical line of ultrasound data across the M-mode image or with a B-mode frame.

The M-mode image is like a strip recorder that flows from right to left at a given rate. The pressure data and, if used, the ECG data, and respiration data, can also continuously sweep right to left synchronously with the M-mode image. The M-mode image with the synchronously displayed pressure and/or ECG data can be frozen at any point in time allowing for any point along the. M-mode image, any point along the pressure curve, or any point along the ECG display to be accurately matched on the display.

The system or method described herein can be used to analyze the cardiovascular system of the subject **114**, including the beating of the heart or other pulsatile dynamics within the cardiovascular system, such as the dynamics of the aorta during systole and diastole.

The analysis of pressure data and dimension data from the image can be performed using software. In the example of the heart, the collected ultrasound data can be used to produce an M-mode image or a B-mode frame. In the M-mode image, two opposed waveforms (**620** and **618**) represent surfaces of the heart which contract and relax throughout the cardiac cycle. A B-mode frame comprises a depth and width dimension and can represent a cross sectional view of an imaged organ. For example, a cross sectional image of a heart can be imaged on a B-mode frame. The cross sectional image may include a lumen and luminal walls, which can he traced on the B-mode frame. The area and/or volume of a trace at a given cross section can be determined and can he correlated with a pressure reading having the same time stamp as the B-mode frame.

As described in greater detail below, any portion of the M-mode image or B-mode frame can be simultaneously or synchronously displayed with the corresponding pressure and/or ECG data such that a shift of the diameter of the ventricles, atria, or imaged portions thereof can be accurately compared with the pressure curve and/or ECG curve to allow simultaneous determination of pressure/dimension/volume relationships of the heart. Accurate determination of the pressure/dimension relationship and/or pressure/volume relationship of the heart can be used to produce pressure/dimension curves (loops) (FIG. **7**) and/or pressure/volume curves (loops) (FIG. **12**) that can be used to analyze physiological parameters of the heart.

FIG. **2** is a block diagram further illustrating the imaging system **100** of FIG. **1**. The system **100** operates on a subject **114** and the ultrasound probe **106** can he placed in proximity to the subject **114** to obtain image information. As such, the ultrasound probe **106** can comprise a transducer for transmitting and receiving ultrasound to and from the subject, respectively. Such a transducer can comprise a single element transducer or an array, and can transmit and receive ultrasound at both clinical and high frequencies. Optionally, the center frequency of the transponder operates at or above 20 MHz.

The systems and methods for capture and display of blood pressure and ultrasound data can be implemented using a combination of hardware and software. The hardware implementation of the system can include any or a combination of the following technologies, which are all well known in the art, such as, discrete electronic components, a discrete logic circuit(s) having logic gates for implementing logic functions upon data signals, an application specific integrated circuit having appropriate logic gates, a programmable gate arrays) (PGA), a field programmable gate array (FPGA), and the like.

An exemplary imaging system **100** includes an ultrasound system **131**. As described above, the ultrasound imaging system **131** described herein is an example of a processing system. The ultrasound system **131** can include a control system **127**, a scan converter **129**, a transmit subsystem **118**, a receive subsystem **120**, and a user input device **136**. The processor **134** is coupled to the control subsystem **127**; and the display **116** is coupled to a processor **134**. The memory **121** is coupled to the processor **134**. The memory **121** can be any type of computer memory and can be referred to as random access memory (RAM) in which software **123** and other software (**140**, **142**) of the ultrasound imaging system executes. Other software may include capture software **140** and analysis software **142**.

The software for the system can comprise an ordered listing of executable instructions for implementing logical functions, and can he embodied in any computer-readable medium for use by or in connection with an instruction execution system, apparatus, or device, such as a computer-based system, processor-containing system, or other system that can fetch the instructions from the instruction execution system, apparatus, or device and execute the instructions.

Memory **121** can also includes image data and pressure data (i.e., collected data **110**) obtained by the imaging system **100**. Collected data **110** can also include ECG data, respiration data and temperature data received by the ultrasound system. The processor **134** is coupled to the control subsystem **127** and the display **116** is coupled to the processor **134**. A memory **121** is coupled to the processor **134**. Software **123**, **140**, **142** controls the acquisition, processing and display of the ultrasound data and blood pressure data allowing the ultrasound system **131** to display an image including blood pressure data and may be used to determine pressure dimension or pressure volume relationships. Memory **121** can also include the collected data **110** obtained by the ultrasound system **131**.

A computer readable storage medium **138** is coupled to the processor for providing instructions to the processor **134** to instruct and/or configure the processor **134** to perform steps or algorithms related to the operation of the ultrasound system **131**. The computer readable medium can include hardware and/or software such as, by the way of example only, magnetic disk, magnetic tape, optically readable

medium such as CD ROMs, and semiconductor memory such as PCMCIA cards. In each case, the medium can take the form of a portable item such as a small disk, floppy disk, cassette, or may take the form of a relatively large or immobile item such as a hard disk drive, solid state memory card, or RAM provided in the support system. It should be noted that the above listed example mediums can be used either alone or in combination.

In the context of this document, a "computer-readable medium" can be any means that can contain, store, communicate, propagate, or transport the program for use by or in connection with the instruction execution system, apparatus, or device. The computer readable medium can be, for example but not limited to, an electronic, magnetic, optical, electromagnetic, infrared, or semiconductor system, apparatus, device, or propagation medium. More specific examples (a non-exhaustive list) of the computer-readable medium can include the following: an electrical connection (electronic) having one or more wires, a portable computer diskette (magnetic), a random access memory (RAM), a read-only memory (ROM), an erasable programmable read-only memory (EPROM or Flash memory) (magnetic), an optical fiber (optical), and a portable compact disc read-only memory (CDROM) (optical). Note that the computer-readable medium could even be paper or another suitable medium upon which the program is printed, as the program can he electronically captured, via for instance optical scanning of the paper or other medium, then compiled, interpreted or otherwise processed in a suitable manner if necessary, and then stored in a computer memory.

The control subsystem **127** is used to direct operation of various components to the ultrasound system **131**. The control subsystem **127** and related components can be provided as software for instructing a general purpose processor or as specialized electronics in a hardware implementation.

The ultrasound system **131** includes a scan converter **129** for converting the electrical signals generated by the received ultrasound echoes to data that can he manipulated by the processor **134** and can be rendered into an image on the display **116**. The control subsystem **127** is connected to a transmit subsystem **118** to provide an ultrasound transmit signal to the ultrasound probe **106**. The ultrasound probe **106** in turn provides an ultrasound receive signal to the receive subsystem **120**. The receive subsystem **120** also provides signals representative of receive signals to the scan converter **129**. The receive subsystem **120** is also connected to the control subsystem **127**. The scan converter **129** is directed by the control subsystem **127** to operate on the received data to render an image for display using the collected data **110**. The collected data **110** can, include, but is not limited to, the image data and blood pressure data. The receive subsystem **120** includes a subcomponent **150** which comprises time-stamp logic or a clock that can stamp received ultrasound signals from the ultrasound probe **106** with a temporal stamp identifying the data with a time identifier. The time identifier identifies data by the time it was collected from the subject **114** and/or when the data was delivered to or received by the receive subsystem **120**. Pressure data and image data can be stamped by the same clock.

The imaging system **100** can further comprises a pressure detecting device **104** for obtaining blood pressure signals from the subject **114** and for converting the pressure signal received from the subject **114** into an analog waveform for delivery to a variable gain amplifier **108**. As shown in FIG. **3**, the variable gain amplifier can have seven levels of control and has three control bits. The gain can be controlled by the software **123** of the ultrasound system **131**. The variable gain amplifier **108** allows for different input depending on the pressure detection device **104** used.

The imaging system **100** can further comprise a level shifter **112** which shifts the analog waveform from the variable gain amplifier **108** and delivers the shifted blood pressure data to a filter **122** which filters the data to remove data of a selected frequency. For example, a low pass filter can he used, for filtering data having a frequency at 2.5 KHz or greater. The amplified, shifted and filtered data can be delivered to an analog to digital converter **124** where it is converted from analog format to digital format. The digital data can be transmitted via a digital data bus to the receive subsystem **120** for digital processing including time stamping. The analog/digital converter **124** can also receive additional analog data from the subject **114** including ECG data, respiration data, and temperature data for provision along the digital data bus to the receive subsystem **120**.

The ultrasound system **131** transmits and receives ultrasound data through the ultrasound probe **106**, provides an interface to a user to control the operational parameters of the imaging system **100**, and processes data appropriate to formulate still and moving images that represent anatomy and/or physiology which is presented to the user through the interface display **136** or display **116**. Pressure and ultrasound data can be time-stamped for provision to the control subsystem and to the image construction subsystem, and for subsequent processing and/or storage and for synchronous display of pressure waves and M-mode or B-mode ultrasound image data on the display **116** and for subsequent pressure/dimension or pressure/volume analysis.

FIG. **3** is a schematic diagram illustrating portions of the exemplary imaging system **100** used to acquire and deliver pressure data from the subject **114** for the synchronous display and analysis with ultrasound M-mode or B-mode ultrasound data. Components shown in FIG. **3** include a variable gain amplifier **108**, a level shifter **112**, a low pass filter **122**, an analog to digital converter **124**, and a digital data bus **302**.

The variable gain amplifier **108** includes three control bits which can be controlled via software **123** to seven levels. The variable gain amplifier **108** accepts input from the pressure monitoring/detecting device which can convert a pressure signal from the subject into an analog waveform. For example, if a Millar pressure monitor is used, the input into the VGA is typically in analog pressure waveform, varying from about −2.5 volts to +2.5 volts. Depending on the pressure monitor or detecting device used, however, the output, in terms of the analog pressure wave voltage, can vary. For example, if a tail cuff is used, the input into the variable gain amplifier can be in the form of an analog waveform with a swing from about −1.0 volts to +1.0 volts. One skilled in the art would appreciate that other swings of voltages are possible depending upon the input or pressure detecting device used and may be less than a swing of −1.0 to +1.0 volts or may be greater than a swing of −2.5 to 2.5 volts. For example, the variable gain amplifier **108** could accept input of −5.0 volts to +5.0 volts or greater.

The variable gain amplifier **108** allows the user to choose different voltage gains based on the input voltage swing of the analog waveform from the pressure detecting device. The gain of the variable gain amplifier can be set, depending on the input from the pressure-detecting device to provide a signal of −2.5 volts to +2,5 volts to the level shifter **112**. Thus, if the input into the variable gain amplifier is an analog waveform with a −2.5 volts to +2.5 voltage swing, the gain

would be 1. The variable gain amplifier **108** is controlled by three control bits to seven levels of control. The control bits **304** are controlled by software **123** to determine the gain of the variable gain amplifier **108** depending on the input from the pressure detecting device **104**.

In one aspect, the level shifter converts or shifts the input voltage swing to a positive voltage swing. Thus, a swing of −2.5 volts to +2.5 volts is shifted to a positive voltage swing from 0 volts to +5.0 volts. The shifted signal is delivered to a low pass filter **122** which filters out portions of the signal with a frequency at 2.5 KHz or above. This filtering reduces out of band noise and also prevents the aliasing because the A/D converter typically runs at 8.0 KHz. The filtered analog signal is input into a 16 bit analog to digital converter **124** which converts analog input to the digital data output for provision to the ultrasound system **131** along a digital data bus **302**.

FIG. **4** is a block diagram illustrating an exemplary method for the capture and display of M-mode ultrasound data or echo signals and blood pressure data using the exemplary system of FIG. **1** and FIG. **2**. In general, ultrasound data can be captured as a series of lines at the same position of subject's anatomy over time. The captured lines of ultrasound data, along with captured pressure data can be time stamped and synchronously displayed. The pressure data can be displayed as a pressure waveform on a display device.

In block **402**, an ultrasound probe comprising a transducer can be placed in proximity to a subject **114** to transmit ultrasound into the subject and to receive reflected ultrasound signals from the subject. A pressure detection device can be connected to the subject **114** through a lead or leads, allowing for the capture of pressure data and for the transformation of pressure data into an analog pressure wave.

In block **404**, the imaging system **100** can capture a line of ultrasound data and captures a blood pressure reading. Optionally, the blood pressure and ultrasound data can be captured simultaneously from the subject. The captured line of ultrasound data and the captured blood pressure reading can be time-stamped by the ultrasound system **131** using the time stamp logic **150** of the receive subsystem **120**. Synchronous lines of ultrasound data and pressure readings can be identified by having the same time-stamped identifier. In M-mode, a series of data lines can be captured at the same position of the anatomy over time. The line of data can be captured into a buffer. A captured line of ultrasound data can be displayed along with a captured pressure value reading. Because of the common time stamp on the ultrasound data line and the blood pressure reading, the data line and the pressure reading can be matched for synchronous real time display on the ultrasound system.

In block **406**, as is typical to M-mode ultrasound, the display area can be scrolled and the display or screen can be updated with the line of ultrasound data and the pressure value reading captured in block **404**. When the end of the screen is reached on the scroll, the oldest data falls off. As the oldest data falls off, the display can be updated with new lines of ultrasound data and pressure data until the user decides to stop the acquisition process at block **410**.

In block **408**, time-stamped ultrasound data and pressure data can be stored in RAM or on the hard drive of the computer for subsequent display or analysis. In block **410**, the user can decide whether to stop acquisition process. If the answer is no, acquisition process can continue and one millisecond later, a second or new line of ultrasound data along with a second or new pressure reading can be captured at block **404**. Again, the display can be updated with the oldest data falling of and the new ultrasound line and pressure data being updated onto the display as shown in block **406**. The new data can be stored with previously stored data in block **408**. The block of data stored in block **408** can be used for subsequent analysis in a rotating buffer which is filled as data is acquired. When the rotating buffer is full in **408**, the next line of data can push the oldest line of data off of the rotating buffer.

If the user decides at block **410** to stop acquisition, data collection stops and the display can be frozen showing the M-mode image on the display of ultrasound system with a synchronous pressure waveform located on the M-mode image. FIG. **6** shows an exemplary display of ultrasound data and blood pressure data produced using the described method where the blood pressure data can be displayed synchronously with the M-mode image. At the end of the block diagram **400**, the user has stopped acquisition and frozen the display in block **412**. After the user has frozen the image in block **412**, the stored data can be processed and analyzed as shown in FIG. **5**.

FIG. **5** is a block diagram illustrating an exemplary method of processing an M-mode ultrasound image using the exemplary system of FIG. **1** and FIG. **2**. In block **504**, a trace is laid onto the image that was frozen on the display in block **412**. Two traces (**614** and **616**) can he created on the displayed image (FIG. **6**). The analysis software **142** can be used to automatically trace both waveforms **620** and **618**.

One tracing **614** traces the waveform **620** which is at approximately 10.5 mm in the exemplary image and the second tracing **616** traces the waveform **618** which is at approximately 15.0 mm in the exemplary image. Software **142** used to trace the waveform can be readily adapted using software for tracing waveforms known to those skilled in the art. Each point on a waveform (**620** and **618**) corresponds to a time-stamped line of ultrasound data acquired approximately 1 millisecond apart. Thus, each point along a trace (**614** and **616**) also corresponds to a time-stamped line of ultrasound data.

The distance (d) between the two traced waveforms or traces represents the dimension of imaged structure, for example, the diameter of the chamber of a heart at the location where ultrasound is being received. In block **506**, a dimension, such as the diameter, volume or area, for each point in the trace can be calculated and/or estimated by using the distance between traces. Each calculated dimension or cross-section has a corresponding timestamp.

In block **508**, pressure can be determined for each point on the pressure waveform and corresponding to a time point on a trace. Thus, the blood pressure from the pressure waveform can be determined for any dimension or volume point along the M-Mode image by matching timestamps along the pressure waveform with the identical time-stamp dimension determined by the two traces using the M-mode image. For example, assuming that the M-mode image is running at 1 KHz, every millisecond a line of data is acquired having a corresponding pressure and dimension. Thus, a new dimension or volume can be determined every millisecond. Readings can be determined quicker or slower than once every millisecond, however, depending on the speed of M-mode operation. For example, the speed may be 8 KHz. Thus, a sampling frequency can vary and can range, for example, from about 1 KHz to about 8 KHz. If the sampling rates are taken at 8 KHz, there are eight more readings per second than at 1 KHz. In one aspect, the pulse repetition frequency (PRF) in M-mode can be used for the sampling frequency:

In block **510**, a graph can be generated using the pressure dimension or pressure volume data generated by the system. For example, a pressure volume or pressure dimension loop can be generated which allows analysis of stroke volume, cardiac output, and elasticity of the myocardium. A graph can also be produced that matches the pressure and dimension with ECG readings to determine volumes and pressures at different points of the cardiac cycle, including at the end of systole. Pressure dimension graphs can be produced using the data produced by the system because a single dimension is measured in M-mode. From the single dimension, an estimate of volume can be performed based on certain assumptions regarding the geometry of the heart.

FIG. **6** is an image of an exemplary display of ultrasound data, blood pressure data, and ECG data produced using the exemplary system of FIG. **1** and FIG. **2**. FIG. **6** represents an exemplary M-mode ultrasound image **600** comprising multiple lines M-mode data displayed with and in synchrony with a pressure waveform **604** and an ECG trace **606**. The M-mode looks across an axial line of data in real time and individual lines of data can be collected at a rate of 1 KHz. At 1 KHz, one line of data is acquired and captured every one millisecond.

During systole and diastole the walls of the heart **602** and **622** contract and relax such that the diameter of the heart chambers move dynamically throughout the heart cycle. As described above, the contraction and relaxation of the walls of the heart produce two waveforms (**620** and **618**) representing the distance of the heart walls (**602** and **622**) from the transducer when viewed in M-mode. These waveforms can be traced automatically by software which produce traces **614** and **616**, wherein **614** traces a surface **620** of the heart closer to the transducer and **616** traces a surface **618** of the heart more distant from the transducer. For example, and as described above one waveform/trace is located at approximately 10.5 mm in depth and the other waveform/trace is located at approximately 15 mm in depth. The dimension or diameter of the lumen **608** of the imaged heart chamber, which is located in the space between the two surfaces (**620** and **618**), can be determined by measuring distance between the two traces at any point along the trace. Similarly, the pressure at any given point along the pressure trace **604** can be correlated with its synchronous point on a waveform of the heart surface by placing a cursor at a given point on the waveform, for example at point **610**, wherein a corresponding line or other designating mark can be made along a pressure trace **604**. For example, the linear mark **612** corresponds to the same point of identical timestamp as the cursor point **610**, which is located along the waveform **620** of the wall **602**. Also as shown in FIG. **6**, the M-mode image and pressure waveform can be synchronized with an ECG trace **606**, such that the pressure diameter and/or volume can be correlated synchronously with a given point in the electrical cycle of the heart.

FIG. **7** is a schematic showing a pressure dimension loop graph and associated events in a typical cardiac cycle. Synchronous pressure/dimension or pressure/volume data can be attained by the display as shown in FIG. **6** using the methods described herein, and can be used to produce a graph relating dimension to pressure. Such a graph is called a pressure to dimension loop, an example of which is shown in FIG. **7**. Through the pressure to dimension loop, the pressure within the chamber of the heart, as well as the dimension at the synchronous time of that pressure can be followed through the different phases of the heart cycle including the filling, mitral valve closure, isovolumetric contraction, aortic valve opening, ejection, aortic valve closure, isovolumeric relaxation, and mitral valve opening. Moreover, many parameters important to heart functioning can be determined by the pressure dimension graph which can be valuable for diagnosing cardiac disease or studying effects of therapeutics on cardiac function.

FIG. **8** is a block diagram illustrating an exemplary method **800** for the capture and display of a B-mode frame or B-mode frames and blood pressure data using the exemplary system of FIG. **1** and FIG. **2**. In Block **802**, an ultrasound probe comprising a transducer can be placed in proximity to the subject **114** to transmit ultrasound into the subject **114** and to receive reflected echo signals or data from the subject. A pressure detection device **104** can be connected to the subject **114** through a lead or leads allowing for the capture of pressure data and for the transformation of pressure data into an analog pressure wave.

In Block **804**, a frame of B-mode ultrasound can be acquired, and a pressure trace can be acquired using the methods and systems described above. Optionally, the blood pressure and ultrasound data can be captured simultaneously from the subject. During the time it takes to acquire a full B-mode frame, a plurality of blood pressure readings can be acquired by the system. In M-mode, for each line of acquired data there can be a corresponding acquired pressure data reading. For a frame of B-mode, there can be multiple pressure readings corresponding to the frame B-mode ultrasound data. One or more pressure reading can therefore be acquired per B-mode frame.

A B-mode frame can be acquired over a time period that can vary depending on the frame rate used to acquire the ultrasound data. The frame can vary from, for example, about 30 to about 230 frames per second (fps) and can be selected by the user depending on factors known to one skilled in the art For example, a given frame rate can be selected based on heart rate, which can vary between the species imaged or other imaging conditions. Thus, for example, a frame rate allowing for the capture of at least about 5 to at least about 10 frames per heart cycle can be selected. Optionally, the selected frame rate is about 100 frames per second. Since the time for acquiring a B-mode frame time may vary depending on the frame rate, the number of pressure readings acquired during the time to acquire one B-mode frame can also vary.

The end of acquisition of the frame can be used as a time to give the frame a time stamp identifier. Any portion of the frame, however, including, but not limited to, the end of acquisition, the beginning of the acquisition, or any point there between, can be used as the time to time stamp an acquired frame.

Once a frame is acquired and time-stamped in Block **804**, that frame can be drawn to the screen in Block **806**. In block **806**, the display can be updated with the frame acquired in Block **804** and with the pressure readings taken during the time in which the frame was taken in **804**. Thus, the display in **806** can show a frame acquired in Block **804**, along with a pressure waveform acquired during the time in which the frame was acquired in Block **804**. FIG. **11** is an image of an exemplary display comprising a frame of B-mode ultrasound data **1100**, and a pressure waveform **1110**. The segment of the pressure waveform that corresponds to the time in which the frame was acquired can be displayed on the display with the acquired B-mode frame. An indicator **1120**, which corresponds to the time stamp of the acquired frame **1100** can be placed on the pressure waveform **1110**.

FIG. **10** is a schematic diagram illustrating two exemplary B-mode frames and an exemplary blood pressure waveform. FIG. **10** shows two B-mode frames **1010** and **1020** as would

be displayed in Block **806**. Each frame can be displayed independently or in a loop. When a loop is shown, a plurality of frames can be viewed in series to form a loop with each frame representing a frame of that loop. Thus, in FIG. **9**, two exemplary frames of a loop are shown. The three dots between the frames schematically represent three additional frames taken between frame **1010** and **1020** that can be used to make up the loop. Two or more frames can be used to comprise a loop.

Below the two exemplary frames is an exemplary blood pressure waveform **1030**. An indicator **1040** is superimposed onto the exemplary waveform **1030** to indicate the place in the waveform that corresponds to the timestamp of the current frame. "Current frame" means the frame that is currently being displayed on the display. However, each frame of a loop can have a separate time stamp, each with a corresponding time-stamped location on the pressure waveform.

In Block **808**, a B-mode frame and the pressure readings can be stored and the system can check to see if the user is trying to stop acquisition at block **810**. In Block **810**, it can be determined whether to stop acquisition of ultrasound data and/or blood pressure data. If the user has tried to stop acquisition, then the display can be frozen and data collection can be stopped in Block **812**. If the user has not tried to stop acquisition, another B-mode frame can be acquired along with a pressure reading, both of which can be time-stamped as described in Block **804**, and the method can he repeated through the steps of the block diagram as described above.

Once a B-mode frame is frozen on the display with a corresponding pressure waveform, processing of the displayed image, including the B-mode frame and pressure trace, can be performed as shown in the exemplary method **900** as shown in FIG. **9**.

FIG. **9** is a block diagram illustrating an exemplary method of processing a B-mode frame or B-mode frames and blood pressure data using the exemplary system of FIG. **1** and FIG. **2**. In Block **904**, a user traces the endocardium or other surface of the imaged organ, structured, or portion thereof, on the first or any B-mode frame acquired in Block **804**. An exemplary tracing of endocardium on a B-mode frame that would be produced by a user in Block **804** is shown in FIG. **10** as **1050** on B-mode frame **1010** and by trace **1060** on B-mode frame **1020**.

An exemplary tracing **1140** is also shown on an exemplary frame in FIG. **11**. FIG. **11** is an image of an exemplary display of a B-mode frame and blood pressure data produced using the exemplary system of FIG. **1** and FIG. **2**. Endocardium or another structure to be traced, such as a surface of any organ, the luminal surface of an organ comprising a cavity, or, for example, the inner surface of the aorta or a heart chamber can be traced manually by a user, working at the human machine interface **136**. The user can draw an exemplary trace onto the display **116** by tracing manually the inner surface of the endocardium or other desired surface.

The surface can also be automatically traced using software **142**., and once a trace is placed on a given frame, such as trace **1050** on frame **1010** of FIG. **10**, then software **142** can automatically place a trace on each subsequent frame acquired, such as trace **1060** on frame **1020** of FIG. **10**. Thus, a user may, in one example, trace a given structure and software **142** can automatically trace that structure through each subsequently acquired frame. Software used to trace the structure automatically between frames can be readily adapted using algorithms and software known to those skilled in the art. The process of tracing the structure can be automated or user-assisted automated. By user-assisted automated means that the user would place the first trace, for example, trace **1050** of FIG. **10** which is shown by a polygon traced by the user, and then the software would automatically place the trace **1060** on frame **1020** or any frame taken subsequent to frame **1020**. The user can also adjust the traces automatically placed by the software to more closely follow the desired structure or, if automated software is not used, the user can manually place a trace on any frame taken from which the user desires to acquire data.

Automatic tracing by software on successive frames is shown in Block **906**. The result of the processing that occurs in Block **906** is one of a series of B-mode ultrasound frames with a traced polygon or other geometric structure representing a surface of traced structure. The area can be calculated based on points of the polygon, examples of which are as shown in FIG. **11**. In FIG. **11**, multiple points **1150** are shown on the trace, which can be used to determine the area of the polygon using the software **142**. The software can use algorithms known in the art.

Using other known formulas, the area can be converted into a volume reading or a volume estimate to determine the volume of the lumen of the organ or portion thereof that has been traced at that cross-section, or at the point where ultrasound has been transmitted and received for that particular B-mode frame. Thus, for example, the volume of a ventricle can be estimated by tracing the inner surface of the ventricle on the display, by determining the area within the traced geometry, and by converting the area using known formulas to a volume estimate of the ventricle.

The volume estimate can be based on the B-mode flame with a time stamp from which the volume estimate was produced. The pressure waveform can have a corresponding time stamp. Thus, as shown in **910**, pressure can be determined for each volume by matching the time stamp of the frame or frames with the corresponding point of the blood pressure waveform.

In Block **912**, a graph, such as a pressure/volume graph can be produced similar to the pressure/dimension graph produced using the M-mode method. An exemplary pressure volume graph that can be produced is shown in FIG. **12**. FIG. **12** is a schematic diagram showing a pressure volume loop graph and associated events in a typical cardiac cycle. The difference between M-mode and B-mode in this instance is that with M-mode, a dimension is acquired. The dimension in the M-mode graph is diameter. Whereas, in B-mode, an area can be acquired that can be converted to volume for a pressure to volume graph.

The foregoing detailed description has been given for understanding exemplary implementations of the invention only and no unnecessary limitations should be understood there from as modifications will be obvious to those skilled in the art without departing from the scope of the appended claims and their equivalents.

Unless otherwise expressly stated, it is in no way intended that any method set forth herein be construed as requiring that its steps be performed in a specific order. Accordingly, where a method claim does not actually recite an order to be followed by its steps or it is not otherwise specifically stated in the claims or descriptions that the steps are to be limited to a specific order, it is no way intended that an order be inferred, in any respect. This holds for any possible non-express basis for interpretation, including: matters of logic with respect to arrangement of steps or operational flow;

plain meaning derived from grammatical organization or punctuation; and the number or e of embodiments described in the specification.

What is claimed is:

1. An ultrasound imaging system, comprising:

an ultrasound imaging probe configured to:

transmit ultrasound energy into a selected portion of a subject,

receive ultrasound echoes from the subject, and

produce ultrasound data signals representative of the received ultrasound echoes;

a blood pressure sensor configured to produce blood pressure data signals representative of a blood pressure of the subject;

a clock configured to assign temporal identifiers to the ultrasound data signals and the blood pressure data signals:

a processing system configured to construct one or more ultrasound image frames using a portion of the ultrasound data signals, wherein the processing system is further configured to generate a dynamic representation of a calculated relationship between a dimension of a structure in one or more of the ultrasound image frames and the blood pressure of the subject using a portion of the blood pressure data signals: and

a display configured to output the generated dynamic representation, wherein the display is configured to display a portion of at least one frame of the one or more ultrasound image frames having a first temporal identifier in temporal synchrony with a portion of a blood pressure waveform corresponding to the blood pressure data signals having the first temporal identifier.

2. The system of claim **1**, wherein the calculated relationship is a pressure-to-volume relationship.

3. The system of claim **2**, wherein the dynamic representation of the calculated relationship is a pressure-to-volume loop curve.

4. The system of claim **1**, wherein the ultrasound imaging probe includes a transducer configured to operate at a center frequency of 20 Megahertz (MHz) or higher.

5. A method of operating an ultrasound imaging system to assess cardiac function of a subject, the method comprising:

receiving ultrasound image data and blood pressure measurement data collected from the subject at a plurality of times;

assigning temporal identifiers to the ultrasound image data and the blood pressure measurement data;

calculating, by the ultrasound imaging system, a pressure-to-volume relationship using a portion of the ultrasound image data having a first temporal identifier and a portion of the blood pressure measurement data having the first temporal identifier; and

displaying, by a display, a dynamic representation of the pressure-to-volume relationship

wherein displaying the dynamic representation comprises displaying a portion of the ultrasound image data having a first temporal identifier in temporal synchrony with a portion of the blood pressure measurement data having the first temporal identifier.

6. The method of claim **5**, wherein the ultrasound image data from a first time of the plurality of times includes an ultrasound image of an organ located within the subject or a portion of an organ located within the subject, and the method further comprises determining a dimension of the organ or portion thereof at the first time by measuring a distance between a first selected portion of the ultrasound image and a second selected portion of the ultrasound image.

7. The method of claim **6**, wherein calculating includes comparing the determined dimension at the first time with a blood pressure measurement collected at the first time to determine the pressure-to-volume relationship for the first time.

8. The method of claim **7**, wherein the ultrasound image data from a second time of the plurality of times includes an ultrasound image of the organ located within the subject or a portion of the organ located within the subject, and the method further comprises determining a dimension of the organ or portion thereof at the second time by measuring a distance between a first selected portion of the ultrasound image at the second time and a second selected portion of the ultrasound image at the second time.

9. The method of claim **8**, wherein calculating includes comparing the determined dimension at the second time with a blood pressure measurement collected at the second time to determine the pressure-to-volume relationship for the second time.

10. The method of claim **5**, wherein the dynamic representation includes a pressure-to-volume loop.

11. The method of claim **5**, wherein receiving the ultrasound image data comprises receiving ultrasound image data acquired from an ultrasound imaging probe configured to operate at a center frequency of 20 MHz or higher.

12. The method claim **5**, wherein the subject is a small animal.

13. The method of claim **5**, further comprising:

receiving a trace of a structure in a portion of the ultrasound image data;

determining a diameter of the structure; and

calculating a volume of the structure based on the diameter.

* * * * *